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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,234	10/21/2005	Makoto Kobayashi	68116(46342)	6538

21874 7590 05/21/2008
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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
05/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,234	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *5-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/21/05,1/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1) Claims 1 to 17 are pending in the instant application.

Election/Restrictions

2) Claims 5 to 17, and claims 1 to 4 in so far as they relate to SEQ ID NOs: 3 to 5 and 7, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 February of 2008. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. The text in line 12 on page 1 of the specification discusses an amino acid sequence without employing the required sequence identifier. Correction is required. See M.P.E.P. 2422.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 1 to 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass a binding assay that can employ a receptor protein having other than its entire native amino acid sequence and a peptide ligand having other than the natural amino acid sequence of which SEQ ID NO:6 is composed. The limitations "substantially the same" and "partial peptide thereof" encompass polypeptides comprising less that the entire amino acid sequence of a native receptor protein or the thirty six amino acids that make upon human neuropeptide Y. However, the instant specification does not provide the guidance needed to practice the claimed process with a receptor protein or peptide ligand comprising anything less than its entire native amino acid sequence. The only manner described in the instant specification of using the claimed method is in the identification of compounds that have potential medicinal use because of their ability to agonize or antagonize the mammalian neuropeptide receptor protein described therein. The claimed invention is only useful in so far as the receptor protein and peptide ligand employed in the claimed assay respond in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since

> improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Given the complex structure of G protein-coupled receptors in general, one of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments meeting either the "substantially the same" or the "partial peptide" limitation of the instant claims are going to be functional, much less be capable of producing an authentic response. In addition, the fact that neuropeptide Y is only thirty six amino acids in length, one has no reasonable expectation that it will tolerate any change in that sequence. Because the instant specification does not identify those amino acid residues in SEQ ID NO:1 or 6 which are critical to the structural and functional integrity of a neuropeptide receptor protein comprising that sequence or a peptide ligand thereto, identify structurally analogous proteins for which this information is known and could be applied to a neuropeptide or neuropeptide receptor protein of the instant invention by extrapolation, or even provide a single working example of an intentionally modified neuropeptide or neuropeptide receptor protein comprising anything less than its entire native amino acid sequence, an artisan can not change or delete even a single residue within the amino acid sequence of SEQ ID NO:1 or 6 and

predict the effects of that change on the performance of that protein or peptide "by resort to known scientific law". Unless one can predict, with reasonable confidence, that the interaction between an intentionally modified neuropeptide receptor protein and a modified neuropeptide ligand is going to produce a response that is predictive of a native ligand-receptor interaction, the information obtained from a process that uses a modified protein and/or a modified peptide is of no practical value.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 1 to 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) Claims 1 to 4 are vague and indefinite because the metes and bounds of the limitation "substantially the same" are undeterminable.

6.2) Claims 1 to 4 are vague because the phrase "or signal transduction" make no sense at all in the context in which it appears in these claims.

6.3) Claims 3 and 4 are vague and indefinite because the limitation "which is characterized by" does not specifically indicate if the limitations that follow are required for the kit.

6.4) Claims 1 and 2 provide for the use of a plurality of reagents in a "method of screening", but, since these claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.\

7) Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

8) The prior art of record did not disclose or suggest neuropeptide Y as an agonist for those receptors known therein as FPRL1 and FPRL2 or that the agonist activation of either of these receptors inhibited forskolin stimulate adenylate cyclase activity in a mammalian cell expressing that receptor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/
Primary Examiner, Art Unit 1649